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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,376	10/19/2005	Ken Inose	TOYA114.011APC	6992
20995 7590 08/28/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER BERTAGNA, ANGELA MARIE	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 08/28/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	Application No. 10/553,376	Applicant(s) INOSE ET AL.	
	Examiner Angela Bertagna	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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**[DETAILED ACTION]**

***Status of the Application***

1. Applicant's response filed July 3, 2007 is acknowledged. Claims 1-10 are currently pending. In the response, claim 1 was amended. Claims 6-8 are withdrawn from consideration as being drawn to a non-elected invention. Claims 9 and 10 are new.

***Election/Restrictions***

2. This application contains claims 6-8 drawn to an invention nonelected with traverse in Paper No. 20070207. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***New Grounds of Rejection Necessitated by Applicant's Amendment***

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierre et al. (Journal of Clinical Microbiology (1991) 29(4): 712-717; newly cited).

Regarding claim 1, Pierre teaches a method for isolating nucleic acids from a sample containing nucleic acids comprising:

(a) dissolving the sample in a buffer comprising at least one surfactant and at least one salt of a monovalent cation (page 713, column 1, paragraphs 4-5, where Pierre teaches that the sample is dissolved in amplification buffer, which contains the surfactants Tween-20 and Triton X-100 and also KCl)

(b) heating the obtained solution at 80-100°C (page 713, column 1, paragraphs 4-5, where Pierre teaches heating at 95°C)

(c) subjecting the heated solution to gel filtration (page 713, column 2, paragraph 2, where the agarose gel electrophoresis step is a gel filtration step)

(d) collecting a fraction containing nucleic acids (page 713, column 2, paragraph 2, where transfer to a nitrocellulose membrane is collecting a fraction containing nucleic acids).

Regarding claim 2, Pierre teaches that the surfactant is Triton X-100 (page 713, column 1, paragraph 4).

Regarding claims 9 and 10, Pierre teaches heating at 95°C (page 713, column 1, paragraphs 4-5), thereby anticipating the claimed ranges of 90-100°C and 95-100°C.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burdick et al. (EP 0 393 744 A1; cited on IDS) in view of Akane et al. (Biotechniques (1994) 16(2): 235, 237, 238; newly cited).

Burdick teaches methods for isolating nucleic acids from whole blood or peripheral blood mononuclear cells (abstract).

Regarding claims 1, 9, and 10, Burdick teaches a method for isolating nucleic acids from a sample containing nucleic acids comprising:

(a) dissolving the sample in a buffer comprising at least one surfactant and at least one salt of a monovalent cation (column 14, lines 32-39)

(b) heating the obtained solution at 80-100°C (column 14, lines 39-41 teaches heating at 118°C; column 6, lines 33-37 teach heating at 80-120°C or 95-120°C; column 6, lines 16-19 teach heating at 100°C)

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(c) filtering the heated solution (column 6, lines 52-57 and column 14, lines 41-42)

(d) collecting a fraction containing nucleic acids (column 6, lines 52-57 and column 14, lines 41-42).

Regarding claim 2, Burdick teaches that the surfactant is Triton X-100 (column 14, lines 37-38).

Regarding claim 3, Burdick teaches that the salt is NaCl (column 14, lines 38-39).

Regarding claims 4 and 5, Burdick teaches that the sample is a blood sample that comprises eukaryotic cells (column 14, lines 25-35).

Burdick teaches filtering the heated solution through a membrane filter (column 6, lines 52-57 and column 14, lines 41-42), but does not teach conducting a gel filtration step as required by claim 1.

Akane teaches methods of preparing DNA samples for PCR comprising a gel filtration step (page 235).

Regarding claim 1, Akane teaches that degraded DNA and a hemoglobin derivative (hematin) isolated from forensic samples interfere with PCR amplification (page 235, column 2). Akane further teaches that although contaminating hematin may be removed by treatment with bovine serum albumin, ultrafiltration, chelating resin treatment, gel filtration or anion-exchange chromatography, degraded DNA may only be removed using gel filtration (page 235, column 2).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to incorporate a gel filtration step into the nucleic acid purification method taught by Burdick. Since the method of Burdick comprised a PCR amplification step following nucleic acid isolation (column 14, lines 41-44), an ordinary practitioner would have been motivated to

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incorporate a gel filtration step, as suggested by Akane, in order to remove any contaminating degraded DNA fragments that would interfere with the PCR. An ordinary practitioner would have had a reasonable expectation of success in incorporating a gel filtration step into the method of Burdick since both methods were directed to purification of DNA from forensic samples for PCR analysis. Thus, the methods of claims 1-5, 9, and 10 are prima facie obvious in view of the combined teachings of Burdick and Akane.

### ***Response to Arguments***

6. Applicant's arguments, see page 3, filed July 3, 2007, with respect to the rejection of claims 1-5 under 35 U.S.C. 102(b) as anticipated by Colpan, have been fully considered and are persuasive. Colpan does not teach all of the elements of claim 1 as amended, and therefore, the rejection under § 102 has been withdrawn.

Applicant's arguments, see page 4, filed July 3, 2007, with respect to the rejection of claims 1-4 under 35 U.S.C. 102(b) as anticipated by Shigenaga, have been fully considered and are persuasive. Shigenaga does not teach all of the elements of claim 1 as amended, and therefore, the rejection under § 102 has been withdrawn.

### ***Conclusion***

No claims are currently allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

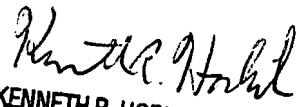
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna  
Art Unit 1637 AMB  
August 20, 2007

amb

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

8/21/07